# PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology – Copiktra Prior Authorization Policy
- Copiktra® (duvelisib capsules – Secura Bio)

**REVIEW DATE:** 06/28/2023

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***INSTRUCTIONS FOR USE***

*THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.*

## CIGNA NATIONAL FORMULARY COVERAGE:

### OVERVIEW

Copiktra, a phosphatidylinositol 3-kinase (PI3K) inhibitor, is indicated for the treatment of adults for relapsed or refractory **chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)** after at least two prior therapies.[1]

### Guidelines

Copiktra is discussed in guidelines from the National Comprehensive Cancer Network (NCCN).

- **CLL/SLL:** NCCN guidelines (version 3.2023 – June 12, 2023) include Copiktra as subsequent therapy for relapsed or refractory disease after prior Bruton tyrosine kinase inhibitor and Venclexta (venetoclax tablets) based regimen in patients without deletion (del)[17p]/TP53 mutation as "other recommended regimens" (category 2A). Copiktra is also recommended as second-line and subsequent therapy for del(17p)/TP53 mutation as "other recommended regimens" (category 2A).[2]
- **T-Cell Lymphoma:** NCCN guidelines (version 1.2023 – January 5, 2023) recommend Copiktra as initial palliative intent therapy or second-line or and subsequent therapy for relapsed/refractory peripheral T-cell lymphoma; as second-line and subsequent therapy for relapsed/refractory disease for breast implant-associated anaplastic large cell lymphoma; and for hepatosplenic T-

cell lymphoma as a single agent for refractory disease after two first-line therapy regimens.[3]

**POLICY STATEMENT**
Prior Authorization is recommended for prescription benefit coverage of Copiktra. All approvals are provided for the duration noted below.

**Copiktra® (duvelisib capsules ( Secura Bio)**
**is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):**

**FDA-Approved Indications**

1. **Chronic Lymphocytic Leukemia.** Approve for 1 year if the patient meets the following (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has tried one systemic regimen.
     Note: Examples of systemic regimens include one or more of the following products: Imbruvica (ibrutinib capsules, tablets, and oral solution); Brukinsa (zanubrutinib capsules), Calquence (acalabrutinib tablets), Venclexta (venetoclax tablets); rituximab; Gazyva (obinutuzumab intravenous infusion); chlorambucil; fludarabine; cyclophosphamide; bendamustine; high-dose methylprednisolone; Campath (alemtuzumab intravenous infusion), or Arzerra (ofatumumab intravenous infusion).

2. **Small Lymphocytic Lymphoma.** Approve for 1 year if the patient meets the following (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has tried one systemic regimen.
     Note: Examples of systemic regimens include one or more of the following products: Imbruvica (ibrutinib capsules, tablets, and oral solution); Calquence (acalabrutinib tablets); Brukinsa (zanubrutinib capsules); Venclexta (venetoclax tablets); rituximab; Gazyva (obinutuzumab intravenous infusion); chlorambucil; fludarabine; cyclophosphamide; bendamustine; high-dose methylprednisolone; Campath (alemtuzumab intravenous infusion); or Arzerra (ofatumumab intravenous infusion).

**Other Uses with Supportive Evidence**

3. **T-Cell Lymphoma**. Approve for 1 year if the patient meets the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets one of the following criteria (i or ii):
     - **i.** Patient meets both of the following criteria (a and b):
       - **a)** Patient has relapsed or refractory disease; AND
       - **b)** Patient has breast implant-associated anaplastic large cell lymphoma or hepatosplenic T-cell lymphoma; OR

**ii.** Patient has peripheral T-cell lymphoma

## CONDITIONS NOT COVERED

**Copiktra® (duvelisib capsules ( Secura Bio) is(are) considered experimental, investigational, or unproven for ANY other use(s).**

## REFERENCES


1. Copiktra® capsules [prescribing information]. Las Vegas, NV: Secura Bio; December 2021.
2. The NCCN Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Clinical Practice Guidelines in Oncology (version 3.2023 – June 12, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 21, 2023.
3. The NCCN T-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 2.2022 – March 7, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 10, 2022.


## HISTORY

| Type of Revision | Summary of Changes | Review Date |
|---|---|---|
| Annual Revision | **T-Cell Lymphoma:** Indication and criteria were added based on NCCN guidelines.<br>**Follicular Lymphoma**: Indication and criteria were removed based on NCCN guideline changes.<br>**Marginal Zone Lymphoma**: Indication and criteria were removed based on NCCN guideline changes. | 11/16/2022 |
| Early Annual Revision | **Chronic Lymphocytic Leukemia:** The requirement that the patient has tried at least two systemic regimens was changed to one systemic regimen.<br>**Small Lymphocytic Lymphoma:** The requirement that the patient has tried at least two systemic regimens was changed to one systemic regimen.<br>**T-Cell Lymphoma:** The requirement that the patient has relapsed, or refractory disease was changed to only apply to patients with breast implant-associated anaplastic large cell lymphoma or hepatosplenic T-cell lymphoma. | 06/28/2023 |